

REMARKS

The Pending Claims:

Claims 46-47 and 49-53 are pending and under active consideration. Claims 1-45 and 48 are canceled. The pending claims are directed to compositions comprising a neuronal sodium channel antagonist of formula Ia and amitraz.

The Amendment:

No claims are currently amended.

The Office Action:

Claim status on the previous submitted claims was allegedly incorrect. Appropriate correction has been made.

Claims 46, 47 and 49-53 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 50-53 are rejected under 35 U.S.C. § 102(b) as being anticipated by Treacy et al. (WO00/54591).

Claims 46, 47 and 49-53 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Treacy et al (WO0054591) in view of Hackett et al (US Patent No. 6,955,818) and Petras (US Patent No. 5,965,137).

Rejection Under 35 U.S.C. § 112

Claims 46, 47 and 49-53 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the failure to recite weight/volume basis for each of the actives and carriers allegedly renders the claim indefinite. Applicants respectfully traverse this rejection based on the following.

According to the Office Action "[t]he weight by volume basis is not specified; so is claim 46 20% of the carrier, the amitraz or the total composition?" Claim 46 recites "[a]n ectoparasitocidal composition which comprises a pharmaceutically acceptable carrier and about 20% w/v of a neuronal sodium channel antagonist ... together with about 10% w/v of amitraz, about 20% w/v of isopropyl myristate and about 10% cineole in diethyl toluamide." Emphasis added. Contrary to the Examiner's assertion, the w/v % as applied to each active is clearly and unambiguously specified in claim 46.

Moreover, a claim is sufficiently definite "if one skilled in the art would understand the bounds of the claim when read in light of the specification." *Exxon Research and Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). A claim is only indefinite if it is "insolubly ambiguous". *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) at 1342.

Claims 46, 47, 49-51 and 53 specify the w/v % for each active and claim 52 unambiguously specifies what the total w/v % is for both actives. Accordingly, the claims are not insolubly ambiguous and a narrowing construction can be properly adopted. As such, the claims are not indefinite. Withdrawal of the indefiniteness rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102

Claims 50-53 are rejected under 35 U.S.C. § 102(b) as being anticipated by Treacy et al. (WO00/54591). Applicants respectfully traverse this rejection based on the following.

For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675.

The Office Action cites Example 1, Table I; page 12, line 16 and page 13 line 16 of Treacy et al., for anticipation of the present claims. Those sections allegedly disclose compositions "at ratios of 100:1, or less of the second compound to Ia. The [total] actives are at 0.01-20%." The total for both actives, specifically amitraz and the compound of formula Ia, in each of the present claims is about 30%. The Examiner has not identified a section in Treacy et al. where the total concentration of both actives is near or about 30% w/v, and certainly nowhere

that specifies the concentration of amitraz and the compound of Formula Ia reach 30%. Treacy et al. discloses the actives in much lower concentrations, and only at the highest, in a generic disclosure, do the actives collectively reach 20% by weight. See p. 13, lines 6-8 of Treacy et al.

Since Treacy et al. does not teach every element of the present claims there is no anticipation. Accordingly, applicants respectfully request that the rejection under 35 U.S.C. § 102 be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 46, 47 and 49-53 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Treacy et al (WO0054591) in view of Hackett et al (US Patent No. 6,955,818) and Petras (US Patent No. 5,965,137). Applicants respectfully traverse this rejection based on the following.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Treacy et al. fails to disclose the presently claimed concentration of amitraz and the compound of Formula Ia in a w/v amount of about 10% and 20%, respectively or 30% collectively. Instead, Treacy et al. individually discloses the actives in much lower concentrations, such as 1-100 ppm (i.e. 0.0001% to 0.01%) or collectively, in a generic disclosure, actives can reach as high as 20% by weight. There is no suggestion in Treacy et al., Hackett et al. or Petras to modify the concentration of amitraz and the compound of Formula Ia to the presently claimed amounts. In fact, such a modification would run counter to Treacy et al.'s intended use in crop control, where dilute amounts are used in actual practice (see page 13, lines 8-12).

Hackett et al. and Petras merely recite additional ingredients/carriers in laundry lists (e.g. IPM) and do not cure Treacy et al.'s deficiencies.

Moreover, assuming *arguendo* that a *prima facie* case of obviousness was established; obviousness based on "optimization" can be rebutted by a showing of unexpected results (see M.P.E.P. § 2144.05(III)). As evidenced in Examples 1-4 (Tables I-IV), the present claimed compositions are extremely efficacious for the topical treatment of parasite infestations on animals, a result that is in no way expected by the prior art. Notably, in Table 4, the claimed composition (row 1) showed even greater efficacy in tick prevention than the successful commercial products: Frontline® and Advantage® over a 4 week study. The composition also showed superior results to

Advantage® in a flea-based study (Table 3). Since parasites can develop resistance to known commercial parasiticides, the development of new treatments is continually needed. The fact that the presently claimed compositions show in some cases superior results to existing and successful commercial products is an indication of the significance of Applicant's discovery. This is in no way expected from the cited references.

Furthermore, pharmaceutically acceptable compositions with a high concentration of metaflumizone and amitraz are particularly difficult to formulate, especially because amitraz is a fairly unstable agent in the presence of particular solvents including those presented in the secondary references (see Talanta, Volume 48, Issue 1, 5 January 1999, Pages 189-199). It was only after considerable formulation studies that viable concentrated solutions of amitraz and metaflumizone as presently claimed were obtained.

Since Treacy et al., Hackett et al. and Petras collectively do not teach or suggest all the claim limitations, and actually teach away from the concentration limitations in the present claims, withdrawal of the obviousness rejection is respectfully requested.

Favorable treatment of the application is earnestly solicited. If it is believed that an interview would expedite prosecution of the application, the Examiner is encouraged to call the undersigned at (973) 660-6615.

Respectfully submitted,

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